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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/051,827 05/01/98 ZIMMERMANN

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EXAMINER

MICHAEL W GLYNN  
NOVARTIS CORPORATION  
PATENT & TRADEMARK DEPARTMENT  
564 MORRIS AVENUE  
SUMMIT NJ 07901-1027

BERCH, M

ART UNIT

PAPER NUMBER

1624

DATE MAILED:

03/29/00

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner of Patents and Trademarks**

<b>Office Action Summary</b>	Application No. <b>09/051,827</b>	Applicant(s) <b>Zimmermann</b>
	Examiner <b>Mark L. Berch</b>	Group Art Unit <b>1624</b>

- Responsive to communication(s) filed on \_\_\_\_\_.
- This action is **FINAL**.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

#### Disposition of Claims

- Claim(s) 1-16 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- Claim(s) \_\_\_\_\_ is/are allowed.
- Claim(s) 1-16 is/are rejected.
- Claim(s) \_\_\_\_\_ is/are objected to.
- Claims \_\_\_\_\_ are subject to restriction or election requirement.

#### Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- The proposed drawing correction, filed on \_\_\_\_\_ is  approved  disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. § 119

- Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All  Some\*  None of the CERTIFIED copies of the priority documents have been
- received.
- received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

#### Attachment(s)

- Notice of References Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). 3
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

Art Unit: 1624

## DETAILED ACTION

### *Claim Rejections - 35 USC § 112*

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4-6 are rejected under 35 U.S.C. 112, paragraphs 1 and 2, as the claimed invention is not described, or is not described in such full, clear, and exact terms as to enable any person skilled in the art to make and use the same, and/or failing to particularly point out and distinctly claim the subject matter which applicant regards as his invention. Specifically:

The page 85 choices starting on line 19 generally do not fit within the definition of R<sub>4</sub>. Hence, these are improperly dependent on claim 1 (paragraph 2) and because these do not fall within the ambit of formula I they have no ascribed utility. Those on lines 19-21 are substituted carbocycles and those on lines 22-27 are substituted heterocycles. However, claim 1 permits substituents on the "aliphatic hydrocarbon radical" but not on the carbocyclic and heterocyclic choices.

Claims 10-13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable

Art Unit: 1624

one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The claim sets forth the treatment of cancer generally. However, there never has been a compound capable of treating cancer generally. There are compounds that treat a range of cancers, but no one has ever been able to figure out how to get a compound to be effective against cancer generally, or even a majority of cancers. Thus, the existence of such a “silver bullet” is contrary to our present understanding in oncology. Even the most broadly effective antitumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the body’s cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally, evidence that the level of skill in this art is low relative to the difficulty of such a task. These compounds inhibit a certain kinase, but there has never been a kinase for which it has been demonstrated that cancerous cells in general are sensitive to the kinase.

Art Unit: 1624

Claims 1-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

1. The dashes in the right ring of Formula I need to be defined.
2. The  $R_1$  definition is unclear. The list appears to end in its first line with the "or", but then continues, and then there is a second "or" in the 4th line of the definition. Some terms are set aside with commas, some with semicolons, which is also unclear. The same problem occurs with the  $R_4$  definition in claim 2 and elsewhere.
3. In fifth from last line of page 83 and also last line: Substituted with what? Likewise page 84 line 3 and elsewhere.
4. The term "acyl" is indefinite. Does this embrace acids of S? P? As? What does the stem look like, i.e. if the acyl is e.g.  $RC(O)$ , what is R? In carboxylic acid acyls, does the carbon count include the carbon of the carbonyl? The claim 2 definition is suggested.
5. "Heterocyclic" is indefinite. What is the size of the ring? What is the number and nature of the heteroatoms? Can the ring be fused or spiroconnected to another ring, and if so, what kind of ring? Can the ring be bridged? Unsaturated?
6. The page 84 choice "hydrocarbyl  $R^\circ$ " is unclear, because in the next line,  $R^\circ$  is set forth as being largely non-hydrocarbyl choices.

Art Unit: 1624

7. The term "thio" in the last line of page 84 is unclear. Is there intended thioxo (=S) or mercapto (-SH)? Whatever choice is selected must be supported by the specification.

8. Claim 7 is unclear; whatever species are desired must be listed

9. In claim 8, the term, "for use ...." simply states an intention, which is a mental step, not a patentable limitation. Hence the claim is improperly dependent, as it does not further limit the claim on which it depends.

10. "Use of" is not a permitted format for US patent claims (*In re Fong*, 129 USPQ 264). (Claims 11-12)

11. The phrase "in accordance ... groups" in the last two lines of page 91 is vague.

WO 98/16528 discloses compounds falling within the claimed genus but is not available as a reference.

*Specification*

The specification must be amended to state that this is a 371 application.

This case lacks an abstract on a separate sheet of paper.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Mark L. Berch whose telephone number is 703-308-4718.

  
Mark L. Berch

Primary Examiner

Group 1610 - Art Unit 1624

March 27, 2000